

ABSTRACT

5 Stable suspensions of a biologically active protein are disclosed that
are suited for aerosol delivery to the lungs of a patient in need of treatment,
which comprise particles of biologically active protein suspended in ethanol.
In a preferred embodiment, the invention describes a stable suspension of
insulin useful for aerosol delivery to the lungs of a patient in need of treatment
10 comprising particles of a pharmaceutically effective amount of insulin
suspended in ethanol. A method of delivering a therapeutically effective
amount of a protein to the respiratory tract of a patient is described which
comprises producing an aerosol of a stable liquid suspension of a protein
using an electrohydrodynamic spraying means wherein the liquid suspension
15 comprises particles of the protein suspended in ethanol. The stable ethanol
suspensions of the invention may optionally contain up to about 20% (V/V) of
a pharmaceutically acceptable formulation additive such as glycerol,
propylene glycol and polyethylene glycol as well as minor amounts (from
about 0.05% to about 5.0% W/V) of a pharmaceutically acceptable excipient.

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